IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: | ) | Art Unit: 1654 |
| LANGE, et al. | ) | Examiner: HA, J. |
| Serial No.: 10/567,406 | ) | Washington, D.C. |
| Filed: October 19, 2006 | ) | August 22, 2007 |
| For: USES OF SECRETAGOGUES | ) | Docket No.: LANGE=6A |
| | ) | Confirmation No.: 2286 |

**ELECTION WITH TRAVERSE**

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S i r :

1. In response to the two-way group level restriction, applicants elect group I with traverse.

2. The group-level restriction is based on an allegation of a posteriori lack of unity, that is, that claim 1 lacks a unifying special technical feature because the only possible unifying feature is shown by Bednarek, USP 6,967,237 (citing column 4, lines 26 and 36-52). We traverse.

Wild-type ghrelin is a 28-amino peptide with a modified internal Ser, depicted on Bednarek col. 2.

Bednarek teaches a truncated ghrelin "having the structure a) $Z^1$-GSXF$(Z)_n$-$Z^2$ [or] b) $Z^1$-GXSF$(Z)_n$-$Z^2$", wherein n is 0-19. See col. 5, lines 5-24. By virtue of the definitions of $Z^1$, $Z^2$, Z and X, peptides (a) and (b) necessarily have a length of exactly 4-23 amino acids ($Z^1$ and $Z^2$ are mere protecting groups).

Under U.S. case law, the term "having" can be interpreted either as "open" (like "comprising") or "closed" (like "consisting of"), depending on context. Since Bednarek teaches that the invention is directed to truncated ghrelin analogues, and that their smaller size is advantageous (see col. 4, line 66 to col. 5, line 4), it follows that Bednarek's formula should not be construed as reading on ghrelin analogs as long as, or longer than, wild-type ghrelin. Thus, Bednarek's "has' must be

interpreted as a "closed" term.

Applicant's claim 1, clause (a), provides

> said ghrelin-like compound or pharmaceutically acceptable salt thereof is 27-28 amino acids in length, with the proviso that said ghrelin-like compound is at least 80 % homologous to SEQ ID NO 1, such as at least 85 % homologous to SEQ ID NO 1

Since Bednarek does not anticipate ghrelin analogues longer than 25 amino acids, it does not anticipate the compounds of applicant's claim 1(a).

Applicant also claims compounds which satisfy (b)

> said ghrelin-like compound is at least 90 % homologous to SEQ ID NO 1.

As Applicant SEQ ID NO:1 consists of 28 amino acids, an analogue under (b) must consist of at least 26 amino acids, since 28x0.9=25.2, and it is not possible to have a "fractional" amino acid. Again, Bednarek does not anticipate.

The group II claims are 33-35. Claim 33, as examined for restriction purposes, claimed

> A method for preventing or treating cancer, comprising administering to an individual in need thereof an effective amount of a ghrelin-like compound in combination with an anti-neoplastic treatment.

However, Bednarek does not teach the combination of administration of a ghrelin-like compound with an anti-neoplastic treatment, in order to prevent or treat cancer.

Moreover, claims 33 and 37 have now been amended to be dependent on claim 1, and claim 39 to include clauses (a) and (b) of claim 1.

Since claims 33-35 are now dependent on claim 1, that is a further reason to rejoin them.

3. Species restrictions have been made.

3.1. Per OA §3 we are required to elect a species of ghrelin analog, as follows:

Different ghrelin analogs: at least 80% homologous to SEQ ID NO:1, at least 85 % homologous to SEQ ID NO:1, at least 90% homologous to SEQ ID NO:1, at least 95% homologous to SEQ ID NO:1, at least 98% homologous to SEQ ID NO:1, Formula I, Formula II, Formula III, or Formula IV, SEQ ID NO:2, SEQ ID NO:3,
Different disorder: catabolic or anorectic,
Different types of cancer: lung, pancreatic, liver, or GI tract,
Different anti-neoplastic treatment: radiotherapy or chemotherapy.

In response, we elect "at least 90% homologous to SEQ ID NO:1", with traverse.

We traverse on the following grounds.

First, this case is subject to PCT unity rules. PCT Administrative Instructions, Annex B, paragraph (c)(i) states, "no problem arises in the case of a genus/species situation where the genus claim avoids the prior art". We have already demonstrated that claim 1 avoids Bednarek.

Secondly, even under domestic unity practice, species must be mutually exclusive. It is clear that "at least 80%" includes, as a subset "at least 90%", and "at least 90%" includes "at least 98%". Formula I includes, as a subset, "at least 80%". It also includes, as subsets, formulae II-IV.

SEQ ID NO:2 differs from SEQ ID NO:1 solely by deletion of Gln-14 and thus is at least 90% homologous with SEQ ID NO:1.

SEQ ID NO:3 differs from SEQ ID NO:1 solely by replacement of Arg-1 Val-12 with Lys-11 Ala-12. That is a change in 2 of 28 amino acids (~7%) so it too is at least 90% homologous with SEQ ID NO:1. See MPEP 806.04(f).

MPEP 806.04(f) warns against restriction between claims, which "overlap in scope".

3.2. OA §5 says that if group I is elected, we must additionally specify all relevant parameters, e.g., if we had elected Formula IV, we would need to elect values for Z1, Z2, X2 and X3. It does not appear that there are any relevant parameters for an election of "at least 90% homologous to SEQ ID

NO:1".

However, if further specificity is required, we elect SEQ ID NO:1, which is a "single disclosed species" of "ghrelin-like compound".

3.3. Returning to OA §3, we elect a catabolic disorder, with traverse on ground that generic claims are allowable.

3.4. Likewise, we elect that the cancer is lung cancer, with traverse on the aforestated ground, and additionally on the basis that election of a cancer species is inappropriate as the treatment is directed to cancer cachexia, a condition not dependent on cancer type.

3.5. It does not appear to us that the species restriction vis-a-vis anti-neoplastic treatment is relevant to group I. However since are seeking rejoinder of group II, we elect radiotherapy.

Respectfully submitted,

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